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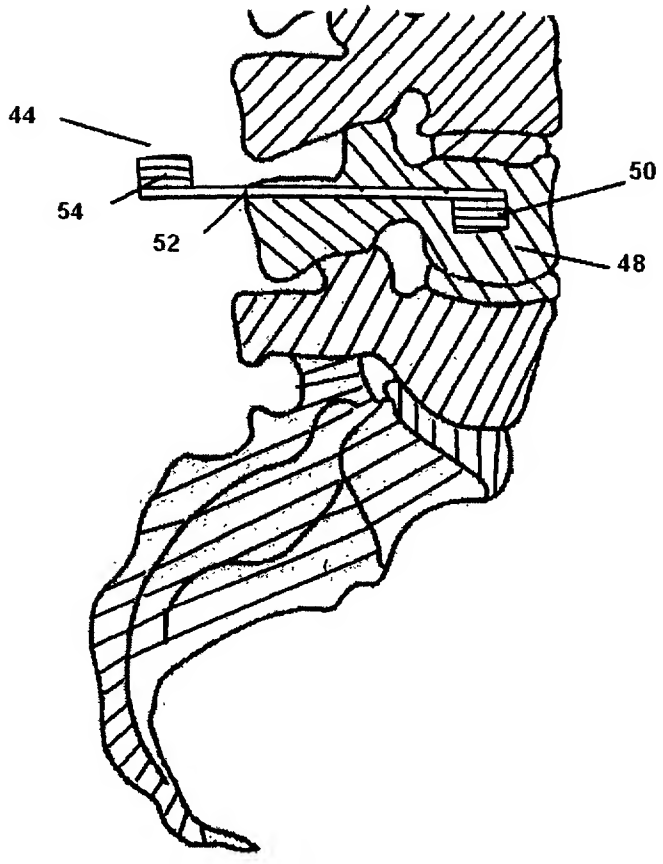

(57) Abstract: The present invention presents a minimally invasive method and device for reconstructing and supporting a fractured or diseased bone, preferably a fractured or diseased vertebra. In addition this invention aims to provide supporting means for a space previously occupied by a diseased intervertebral disc, which has been completely or partially removed. The minimally invasive reconstructing and supporting spiral device comprises a coiled structure made of a coiled strap or for example shape-memory material, whereby the strap is advanced towards a predetermined position in a deployed state and regains a coiled shape within the target position providing a supporting prosthesis.

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MINIMALLY INVASIVE SUPPORT IMPLANT DEVICE AND METHOD

FIELD OF THE INVENTION

The present invention relates to orthopedic implants. More particularly, the present invention relates to minimally invasive support implant device and method.

BACKGROUND OF THE INVENTION

The spinal column serves as the support structure of the body, rendering the body its posture. Yet age, diseases, and traumas cause detriment to its completeness and stability while causing structural failures such as vertebral fractures, disc hernias, degenerative disk diseases, etc. Such detriments result in pain, spinal instability, and even paralysis.

A vertebral column includes 26 vertebras (7 cervical, 12 thoracic, 5 lumbar, 1 sacrum and 1 coccyx) separated by intervertebral fibrocartilage discs. A typical vertebra consists of two essential parts - an anterior segment, comprising the body and a posterior part, comprising the vertebral or neural arch. The vertebral arch consists of a pair of pedicles and a pair of laminæ, and supports seven portions - four articular, two transverse, and one spinous. The body and the vertebral arch define a foramen, knowrt as the vertebral foramen. It should be noted that the vertebras' structure differs slightly according to the position on the spinal column (i.e. cervical, thoracic, lumbar).

Typical vertebral column disorders include traumatic damages such as compression fractures, degenerative disc disease, disc hernias (ruptured or protruded disc), scoliosis (lateral bending of the vertebral column), kyphosis (exaggerated thoracic curvature), lordosis (exaggerated lumbar curvature),

spina bifidia (congenital incompletion of the closure of the vertebral column). Fixation, replacement and reconstructive solutions, both intravertebral and intervertebral were introduced in the past. For example, US Patent No. 6,019,793 (Perren et al.), titled SURGICAL PROSTHETIC DEVICE, discloses a surgical prosthetic device that is adapted for placement between two adjoining vertebrae for total or partial replacement of the disk from therebetween. The device has two plates with interior surfaces facing each other and being held at a distance by connecting means and exterior surfaces for contacting the end plates of the two adjoining vertebrae. The connecting means is made of a shape-memory alloy so that it is delivered to its destination cramped within a delivering tool and deploys once freed in position.

Lin disclosed a locking device and a fusing device, both comprises spiral and elastic elements. US Patent No. 5,423,816 titled INTERVERTEBRAL LOCKING DEVICE discloses an intervertebral locking device comprising one spiral elastic body, two bracing mounts and two sets of locking members. The two bracing mounts are fastened respectively to both ends of the spiral elastic body. The two sets of locking members are fastened respectively with the two bracing mounts such that each set of the locking members is anchored in one of the two vertebrae adjacent to a vertebra under treatment. The spiral elastic body and the vertebra under treatment evince similar elastic qualities, i.e. similar deflection characteristics. A plurality of bone grafts affinitive to the vertebra under treatment is deposited in the chambers of the spiral elastic body and in the spaces surrounding the spiral elastic body. And US Patent No. 5,423,817 (Lin) titled INTERVERTEBRAL FUSING DEVICE, discloses an intervertebral fusing device having a spring body portion interconnecting a first spiral ring mount and a second spiral ring mount. Each spiral ring mount has a spiralling projection on the outer surface. The spring body portion is defined by a plurality of spiral loops. The plurality of spiral loops and spiralling projection of the spiral ring mounts have a constant pitch. A mount cover and a head member are threaded into an internally threaded portion of a respective spiral ring mount thereby forming a chamber in which bone grafts

affinitive to the cells and tissues of a vertebra may be housed. The spring body portion is similar in elasticity to the vertebra.

Mathews teaches in US Patent No. 6,033,406 titled METHOD FOR SUBCUTANEOUS SUPRAFASCIAL PEDICULAR INTERNAL FIXATION a method for internal fixation of vertebra of the spine to facilitate graft fusion includes steps for excising the nucleus of an affected disc, preparing a bone graft, instrumenting the vertebrae for fixation, and introducing the bone graft into the resected nuclear space. Disc resection is conducted through two portals through the annulus, with one portal supporting resection instruments and the other supporting a viewing device. The fixation hardware is inserted through small incisions aligned with each pedicle to be instrumented. The hardware includes bone screws, fixation plates, engagement nuts, and linking members. In an important aspect of the method, the fixation plates, engagement nuts and linking members are supported suprafascially but subcutaneously so that the fascia and muscle tissue are not damaged. The bone screw is configured to support the fixation hardware above the fascia. In a further aspect of the invention, a three-component dilator system is provided for use during the bone screw implantation steps of the method.

US Patent NO. 5,306,310 (Siebels), titled VERTEBRAL PROSTHESIS, disclosed a prosthesis as a vertebral replacement element consisting of two helical strands, which may be screwed together to form a tubular structure. The implant is inserted between vertebrae and then slightly unscrewed until the desired height is reached. The helical strands consist of carbon fiber reinforced composite material.

Generally, the devices and methods described herein and other methods involve a massive surgical involvement and are considered as highly invasive solutions for fixating, replacing and reconstructing vertebras.

Minimally invasive systems and methods are described in US Patent No. 6,248,110 (Reiley et al.) titled SYSTEMS AND METHODS FOR TREATING FRACTURED OR DISEASED BONE USING EXPANDABLE BODIES. In one arrangement, the systems and methods deploy an expandable body in

association with a bone cement nozzle into the bone, such that both occupy the bone interior at the same time. In another arrangement, the systems and methods deploy multiple expandable bodies, which occupy the bone interior volume simultaneously. Expansion of the bodies form cavity or cavities in cancellous bone in the interior bone volume. Use of expandable balloon is also taught. Expendable balloon serves for reconstruction of collapsed bone. In order to fill the space created and provide stabilization to the bone, insertion of polymethylmethacrylate (PMMA) cement, which dries and stiffens, is required.

The problem with PMMA is that it is not suitable for insertion in young people because it tends to loosen and the fixation is jeopardized. In addition, it may involve side effects such as cement leakage and spinal cord compression , Furthermore, the cement is hard to control and maintain during insertion because of its fluidic nature and it prevents bone growth, a parameter that is important for the healing procedure of the bone.

The above-mentioned fixation and support solutions (and others) introduce mechanical structures in which support of fixation is gained. All devices are surgically placed in the desired position. Some of them require a major surgical operation involving major invasive actions. There is a need for a supporting and fixating device that involves minimal invasive actions in order to place the device in the vertebra, for example. Another requirement that is important for fixing and supporting a bone is to provide a solid scaffolding system in order to establish a solid support and full reconstruction.

SUMMARY OF THE INVENTION

It is an object of the present invention to provide a minimally invasive method and device for reconstructing and supporting a fractured or diseased bone, preferably a fractured or diseased vertebra.

It is another object of the present invention to provide a minimally invasive method and device that are aimed at providing support within a space previously occupied by a diseased intervertebral disc, which has been completely or partially removed.

It is yet another object of the present invention to provide a minimally invasive method and device for reconstructing and supporting a fractured or diseased vertebra by using a biocompatible shape memory material such as shape memory alloys, or other biocompatible materials such as stainless steel.

It is therefore provided, in accordance with a preferred embodiment of the present invention,

BRIEF DESCRIPTION OF THE FIGURES

In order to better understand the present invention, and appreciate its practical applications, the following Figures are provided and referenced hereinafter. It should be noted that the Figures are given as examples only and in no way limit the scope of the invention.

Figure 1 illustrates a side view of a vertebral spiral support implant device in accordance with a preferred embodiment of the present invention, implanted within a vertebra.

Figure 2a illustrates a coiled support implant device made of a shape-memory alloy in accordance with another preferred embodiment of the present invention, in four different stages.

Figure 2b illustrates the support implant device shown in Fig. 2a, in an initial stage of its deployment.

Figure 2c illustrates the support implant device shown in Fig. 2a, in a later stage of its deployment.

Figure 2d illustrates the support implant device shown in Fig. 2a, positioned in its final state at the desired destination.

Figure 3 illustrates an initial stage of the insertion of one end of the spring support implant device of the present invention (as shown in Fig. 1) into the vertebra through a pedicle of the vertebra.

Figure 4 illustrates an intermediary stage of the insertion of the spring support implant device of the present invention into the vertebra.

Figure 5 illustrates an intervertebral spiral support implant device in accordance with a preferred embodiment of the present invention, implanted in the intervertebral space between two adjacent vertebrae.

DETAILED DESCRIPTION OF THE INVENTION AND FIGURES

The present invention provides a unique device and a method for repairing damaged bones, primarily damaged or diseased vertebras, especially in cases of compressed fractures of the body of the vertebra caused by trauma or related to osteoporosis. Similarly, although a slightly different approach is required, the present invention may relate to fixation of the spine, in cases of degenerative intervertebral disc disease, where the

structure disclosed herein may serve as intervertebral fixation device similar to an intervertebral cage.

In accordance with a preferred embodiment, the vertebral reconstruction and support implant method is a minimally invasive surgical method, involving insertion of a coil or a spring through a small incision in the skin and surrounding muscle tissue into the vertebral body or into the inter-vertebral disk area, in order to reconstruct the original anatomical structures and/or fill in a space formed due to an injury. The coil is being deployed before the insertion in order to fit the small incision and to ensure minimal invasion. Using a shape-memory alloy, and other kind of biocompatible metal or other biocompatibe durable strong material, the coil in the interior of the vertebra substantially regains its original shape and forms a support to the vertebra.

The device and method of the present invention are suited in particular for collapsed vertebral body or degenerative disk space. After using it for reconstruction of the anatomical structure of the vertebral body, the device is used as a prosthesis that supports the vertebra internally (within the cortex), substantially maintaining the normal original shape of the vertebra and the spinal structure.

The present invention, although not limited to this purpose only, presents a device and method that is particularly suited for treating fractured and compressed bones and more particularly compression fracture of the vertebral bodies. In an alternative embodiment of the present invention it is suggested to implement the spiral support implant device for treating a degenerative disc disease, by replacing the diseased disc or most of it and positioning the spiral support implant device intervertebrally.

The implementation of the present invention requires minimally invasive surgery that significantly reduces damage to adjacent tissues existing around the treated organ, and is usually much faster to perform, reducing surgical procedure time, hospitalization and recovery time, and saving costs.

An important aspect of the present invention is using a method and device to reconstruct anatomical structure, and then use the same device, that

changes its role, serving as a reconstructing and fixing device to be left as an implant in-vivo.

The above-mentioned concept brings about several additional advantages and properties that can be characterized as follows: The present invention introduces a minimally invasive method and approach for treating the affected bone hence causing minimal damage to adjacent tissues and anatomical structures. In addition, it uses a coil-shaped prosthesis to reconstruct a compressed bone back to its normal structure that supports the vertebral body or other structure treated. This is done while saving essential surrounding ligaments muscles and other tissues responsible for providing stabilization of the vertebral column.

Primarily, the purpose of the present invention is to provide a solution for compressed or burst fractured vertebras and it has a real appeal for osteoporosis related compression fractures. However it is asserted that the present invention may be used to treat degenerative disc diseases by replacing an ill intervertebral disc and enhancing spine fixation.

In a preferred embodiment of the present invention, reconstruction of the vertebral body is achieved by inserting a coil preferably made of a shape-memory alloy or other metal based implant through one of the pedicles, while the coil is in a deployed state. The coil regains its original spiral shape in the interior of the vertebra and acts as a reconstructive element or a cage-like fixation. Building an implant inside the treated area is a novel concept and technique of treatment, derived from the need to cause minimum damage to tissue while operating on a patient by employing minimally invasive technique. Other operation techniques of vertebral bones require open surgery, hence creating damage to healthy tissues.

Reference is now made to Figure 1 illustrating a side view of a vertebral spiral support implant device in accordance with a preferred embodiment of the present invention, implanted in a vertebra. A spiral implant support device 10 is inserted into a damaged vertebral body 12. Spiral implant support 10 is positioned in the interior of the vertebra so as to establish support to the

damaged vertebra. The vertebra is reconstructed while the bone is supported by spiral implant support 10, and regains its stability. The spiral implant support structure is made of a shape-memory alloy that regains its original structure after deployment. In order to insert the spiral implant support into the vertebra while employing a minimal invasive surgery method, the implant has to be inserted while deployed. The deployed implant support is inserted into the vertebral body via a drilled bore through the pedicle 14. Typically, the diameter of the bore is anticipated to range between 4 to 8 mm according to the size of the vertebra and its pedicle (but the present invention is not limited to these measurements).

Reference is now made to Figures 2a-2d illustrating a spiral support implant device made of a shape-memory alloy or other metals in accordance with another preferred embodiment of the present invention, in four different stages of its deployment. Generally, the term shape memory alloys is applied to a group of metallic materials such as NiTi, for example, as marketed under the brand name nitinol ™, that demonstrate the ability to return to a previously defined shape or size when subjected to an appropriate condition. It should be noted that metals that are resilient in their nature can be employed also since they regain their original form or substantially their original form. An example for such metal is stainless steel 316 LVM.

A spiral structure 20 made preferably of a memory shape alloy is shown in its original shape, a rolled up structure. The rolled up coiled structure is then deployed to a deployed shape 22 by exerting strain on the structure. The profile of an end 24 of deployed shape 22 is much smaller than the profile of rolled up device 20, and in the deployed state the rolled up structure can be easily inserted into the vertebral body space (through the pedicle, for example) or into the inter-vertebral space, between adjoining vertebrae, filling the space previously occupied by an intervertebral disc, while employing a minimally invasive procedure. The deployed structure can also be inserted to the interior of the bone through an insertion channel (an introduction tool, such as a cannula). When the deployed structure 26 or a portion of it is placed inside the bone, or in the intervertebral space, the shape-memory structure

starts to regain its original shape 28. Finally, when the structure is completely inside the bone (or in the intervertebral space), it regains its shape. Since this embodiment is made up of a continuous strip, the surgeon can decide at any point to cut the deployed structure and insert only an adequate portion of the spiral structure, upon obtaining the desired anatomical support structure.

In order to better understand the method of the present invention in which a spiral support implant device is implanted in the interior of the vertebra, reference is now made to Figure 3, illustrating an initial stage of the insertion of the end of the spiral support implant device of the present invention into the vertebra through a pedicle of the vertebra. The vertebra is accessed in a minimally invasive manner. One end 40 of a coil support implant device 44 is deployed by exerting strain on the coil and holding it substantially in a straightened band formation. The straightened band is inserted through a small incision in the patient's skin and through the muscle tissues towards the vertebra. Side 40 of the spiral implant device is directed to one of the pedicles 14. The coil can be directed also through a delivering tool (a cannula) that is inserted and directed to the desired location prior to the insertion of the spiral implant itself.. It is recommended that end 40 be a pointed end 46 for easier insertion. The pointed end will facilitate the penetration of the coil through the external wall of the vertebra's body, which is made from cortical bone, and into the interior 48 of the vertebra's body, which is made of cancellous or spongeous bone material.

Reference is now made to Figure 4 illustrating an intermediary stage of the insertion of the spiral support implant device of the present invention into the vertebra. The insertion of spiral support implant device 44 is performed in stages. After a portion of the coil has been inserted as a straightened band into the body of the vertebra 48, it is exposed to a temperature of about 37°C. In this temperature, the band regains substantially its original shape and coils. In the intermediate stage shown in Figure 4, a portion 50 of spiral support implant device 44, which is inside the vertebra, is in the shape of a coil, the middle portion 52 of the coil is straightened and being slowly inserted into the vertebra, and the other side 54 of the coil, which is still in its original shape, is

outside the vertebra and the body. The last part could be also done with alloys that are not memory alloys such as stainless steel 316 LVM.

The final stage of the insertion process is shown in Figure 1. The whole spiral support implant device is inserted in the body and is in a coil shape. In this situation, the coil supports and fixes the vertebra's body so that it can go through a rehabilitation process in which the spongeous bone of the interior of the vertebra grown back .

Figure 5 illustrates an intervertebral spiral support implant device in accordance with a preferred embodiment of the present invention, implanted in the intervertebral space between two adjacent vertebrae. The intervertebral spiral support implant device 44 is positioned between two adjacent vertebrae 12, replacing the intervertebral disc.

Note that the present invention may be implemented for providing support to enhance fixation in an intervertebral space previously occupied by a disc. The delivery method may be any minimally invasive approach. Currently, there are some minimally invasive approaches, for example endoscopic. Such methods may be used, possibly with minor adjustments, in conjunction with the present invention.

It is noted that the scope of the present invention is not limited to shape memory alloys and another materials may be employed in the method of the present invention, as long as the material exhibits biocompatibility, strength, and stability. Moreover, researchers are developing materials that are implantable within a bone and during the course of time dissolve or disperse, allowing space for bone material. The present invention may be implemented with such materials as well.

Different coatings may be combined if compatible and beneficial. Coating such as ones that are adhered to the bone and encourage the growth of the bone (bone growth stimulating substance) are mainly desired since the growth of the bone is very important to the healing process of the bone. There are also available and in research processes materials that act as bone substitute or biodegradable bone substitute that degrade as the natural bone

is growing. Other possible materials that can be used as coatings are materials that are adhered to the bone and are antibiotic materials that prevent infection or materials that suppress diseases such as cancer, like antineoplastic substance.

The method described herein is minimally invasive and as such has special appeal, for it substantially minimizes surgery-related infection risks, reduces the surgical procedure steps (and thus the costs involved), and shortens healing and recovery times for the patient.

It should be clear that the description of the embodiments and attached Figures set forth in this specification serves only for a better understanding of the invention, without limiting its scope.

It should also be clear that a person skilled in the art, after reading the present specification could make adjustments or amendments to the attached Figures and above described embodiments that would still be covered by the following Claims and their equivalents.

CLAIMS

1. A minimally invasive reconstructing and supporting spiral device for reconstructing and supporting within a diseased or fractured bone or within an intervertebral space, said device comprising a coiled structure made of a coiled strap of shape-memory material, whereby the strap is advanced towards a predetermined position in a deployed state and regains a coiled shape within the target position providing a supporting prosthesis.

2. The device as claimed in Claim 1, wherein said coil is made of a shape memory material.

3. The device as claimed in Claim 2, wherein the shape memory material is an alloy.

4. The device as claimed in Claim 2, wherein the shape memory material is nitinol.

5. The device as claimed in Claim 1, wherein the coil has a rolled up structure.

6. The device as claimed in Claim 1, wherein said coiled structure is spiral.

7. The device as claimed in Claim 1, wherein the coil is provided with a pointed end so as to facilitate its insertion into the bone.

8. The device as claimed in Claim 1, wherein it is coated with antineoplastic substance.

9. The device as claimed in Claim 1, wherein it is coated with bone growth stimulating substance.

10. A minimal invasive method for reconstructing and supporting within a diseased or fractured bone or within a space previously occupied by a diseased intervertebral disc, the method comprising:

providing a coil made of a material that is adapted to regain its original shape after deployment of the coil;

deploying the coil so as to establish a band having two sides;

inserting a portion of the coil into the bone from one of the sides;

inserting in a gradual manner another portion of the coil when the portion inside the bone regains its coiled shape, until the coil is inside the bone.

11. The method as claimed in Claim 9, wherein the coil is made of a shape memory material.

12. The method as claimed in Claim 11, wherein the shape memory material is nitinol.

13. The method as claimed in Claim 10, wherein the coil is a spring-like coil.

14. The method as claimed in Claim 10, wherein the coil has a rolled up structure.

15. The method as claimed in Claim 10, wherein the method further comprising inserting the coil into the bone through an insertion channel.

16. A minimal invasive method for reconstructing and supporting within a diseased or fractured bone or within a space previously occupied by a diseased intervertebral disc, the method comprising:

providing a coil made of a material that is adapted to regain its original shape;

deploying the coil so as to establish a band having two sides;

providing delivery means having low profile for delivering the coil into the bone;

delivering a portion of the coil into the bone from one of the sides through said delivery means;

delivering another portion of the coil when the portion inside the bone regains its coiled shape until the coil is inside the bone.

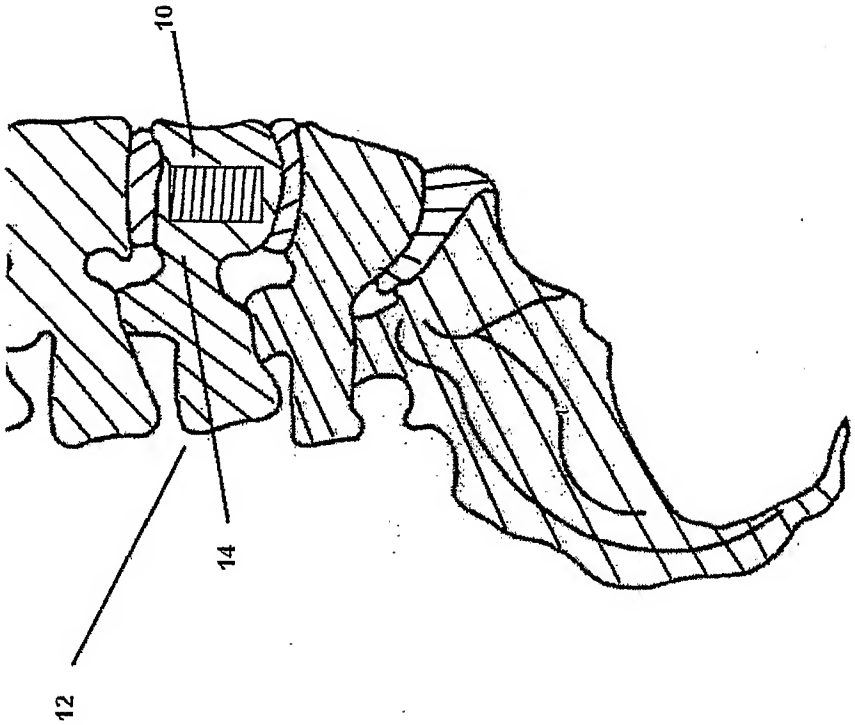

Fig 1

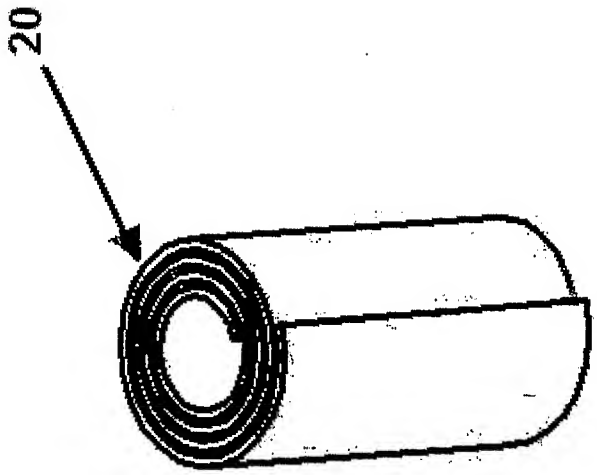

Fig 2a

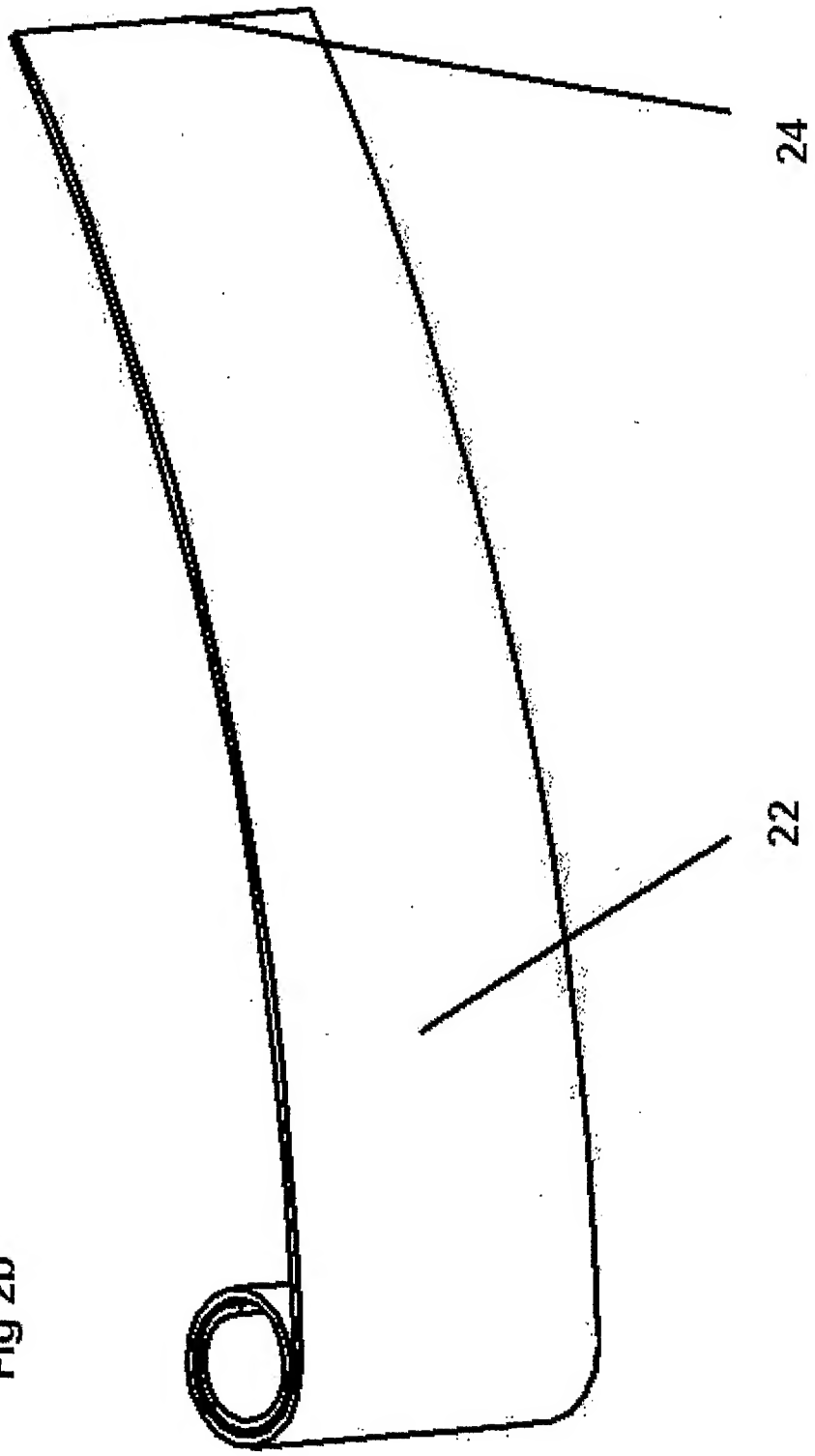

Fig 2b

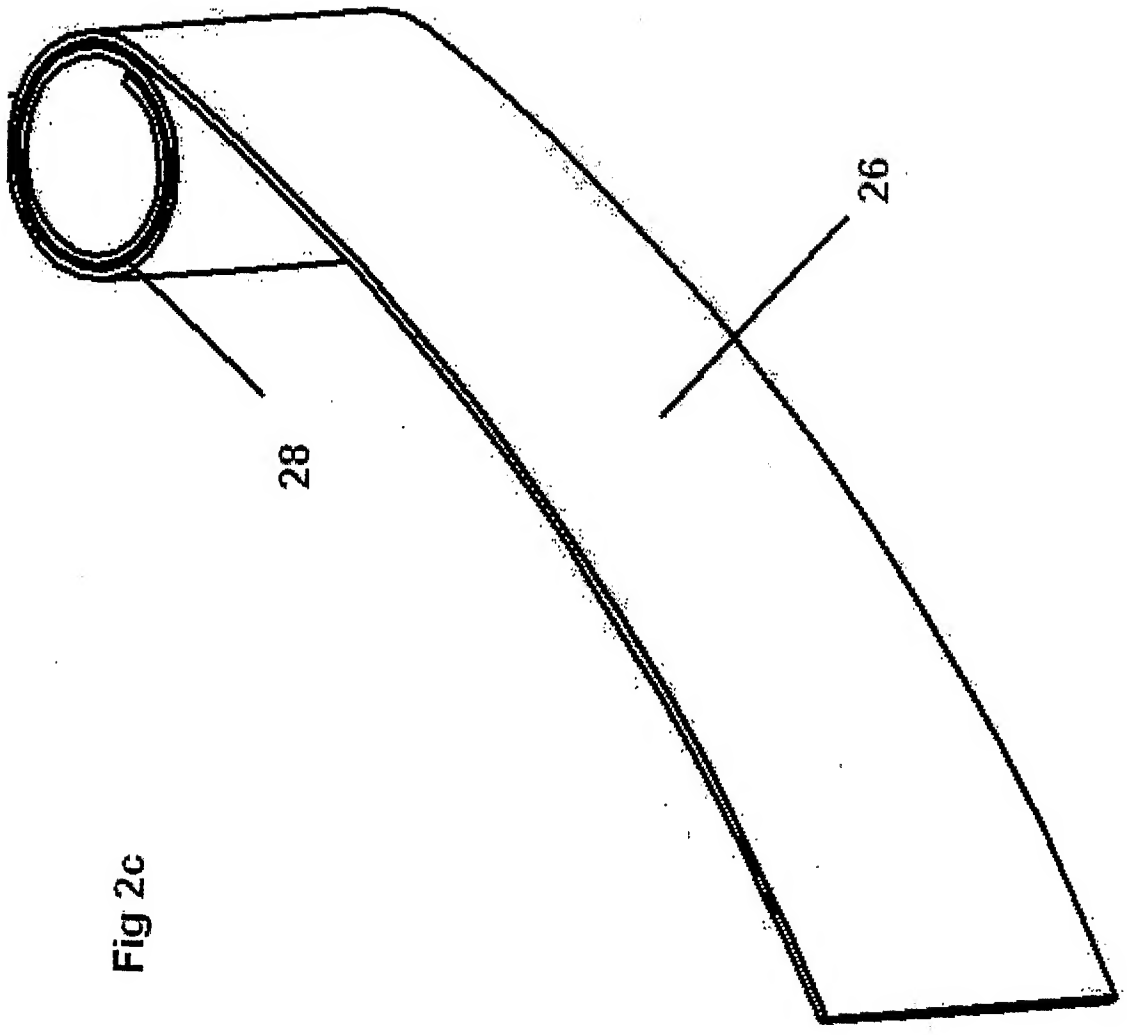

Fig 2c

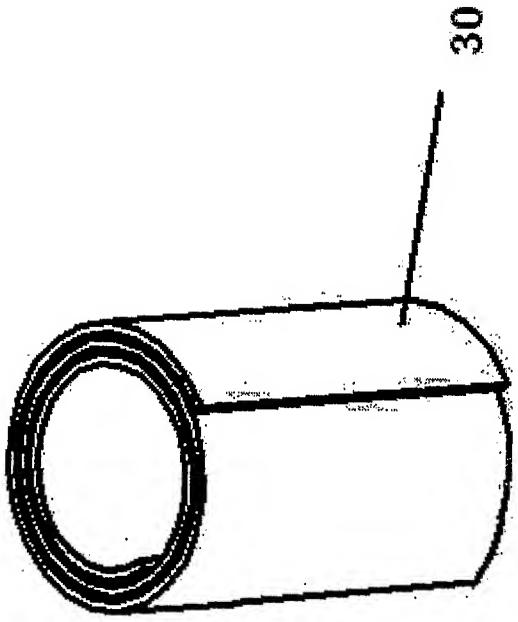

Fig 2d

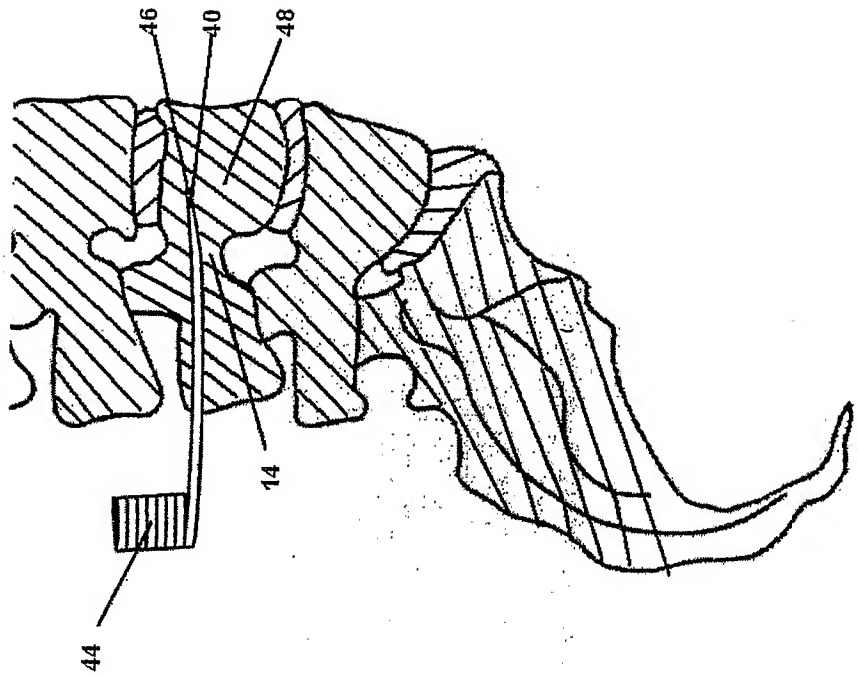

Fig 3

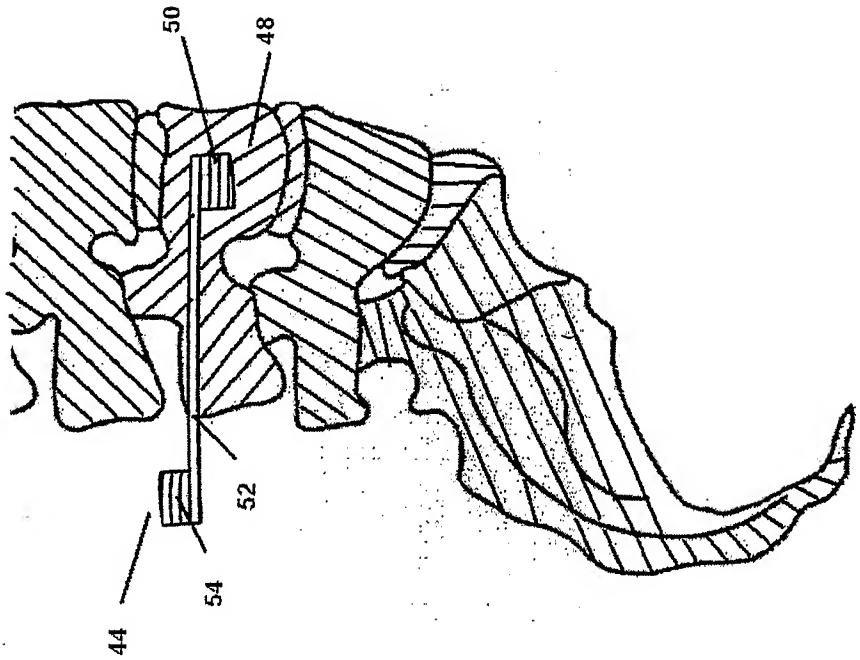

Fig. 4

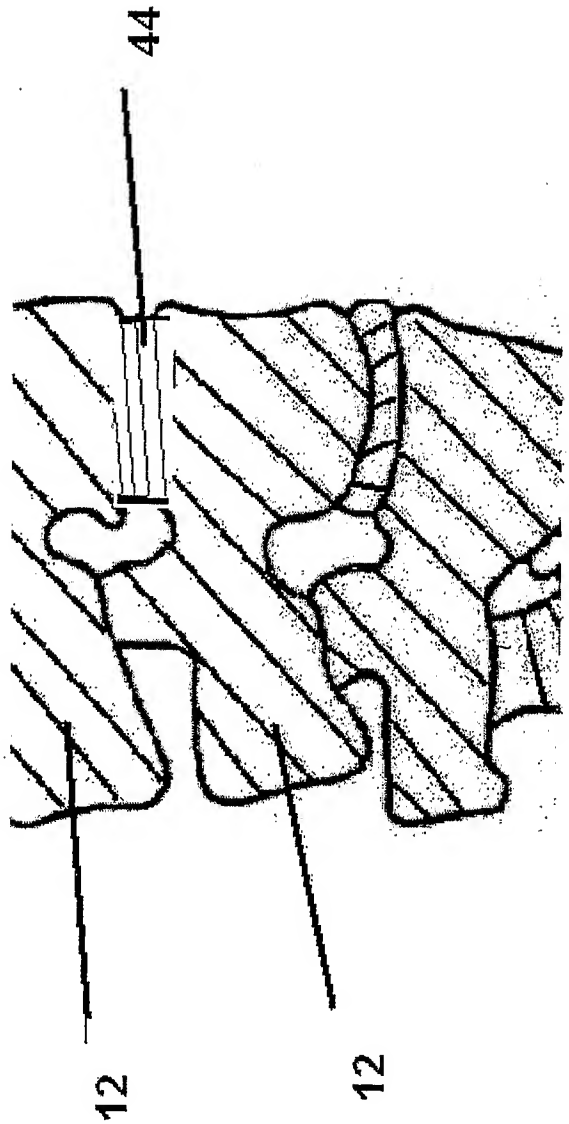

Fig 5